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| 10/581,678 | 09/20/2006 | Zhibing Hu | UNTD-0002 (122302.00085) | 6923 |
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| JACKSON WALKER LLP 901 MAIN STREET SUITE 6000 DALLAS, TX 75202-3797 | | | ARIANI, KADE | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|----------------------------------|
| Office Action Summary | Application No. 10/581,678 | Applicant(s) HU ET AL. |
| | Examiner Kade Ariani | Art Unit 1651 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 September 2009.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-9 and 11-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-9, and 11-46 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement (PTO/1449B)
 Paper No(s)/Mail Date 11/13/2009
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

The amendment filed on September 22, 2009, has been received and entered. Claims 1-9, 11-47 are pending in this application and were examined on their merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 15-28 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn due to Applicant's amendments to the claims filed on 09/22/2009.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 15, 20-27 under 35 U.S.C. 102(b) as being anticipated by Jones et al. (Macromolecules, 2000, Vol. 33, p.8301-8306), is withdrawn due to Applicants' amendments to the claims filed on 09/22/2009.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 and 11-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over of Jones et al. (Macromolecules, 2000, Vol. 33, p.8301-8306) in view of Kurisawa et al. (Journal of Controlled Release, 1998, Vol. 54, p.191-200) and further in view of Cai et al. (Journal of Applied Polymer Science, 2002, Vol. 83, p.169-178).

Claims 15-28 are drawn to a method of preparing an interpenetrating polymer network (IPN) of monodispersed nanoparticles, comprising providing a first monodispersed polymer nanoparticles prepared by mixing first monomer, a surfactant, a first cross linking agent, and first initiator at a first temperature, wherein the first polymer has a low critical solution temperature of between 28°C and 45°C, the first polymerization temperature is above the LCST of the first monodispersed polymer: adding to the first

mono-dispersed polymer a second monomer, a second cross linking agent, a second initiator and an activator, forming a nanoparticle solution wherein the nanoparticle solution is an aqueous solution, mixing the nanoparticles solution for a period of time at a second temperature, wherein the second temperature is below the low critical solution temperature of the first monodispersed polymer, isolating the IPN nanoparticles, (wherein the first monomer, the first cross linking agent, the second monomer, and the second cross linking agent are substantially free from dissolved oxygen gas and the first wherein the first polymer forms a first polymer network which interpenetrates a second polymer network formed by the second polymer, mixing the isolated IPN nanoparticles with a biologically active material at a third temperature, the biologically active material is a drug, wherein the third temperature is below a gelation temperature (T_g) of the IPN nanoparticles in a n aqueous mixture, (and wherein above the T_g the first polymer network consists of cross-linked polymer chains inside each nanoparticle, and the second polymer network consist of a cross-linked system of the nanoparticles), wherein the T_g is about 33°C, wherein the first polymer comprises poly (-N-isopropylacrylamide), the second polymer comprises poly (acrylic acid), the first cross linking agent comprises N, N'-methylenebisacrylamide, potassium persulfate, ammonium persulfate, the surfactant comprises SDS, and TEMED (activator), the IPN of nanoparticles hydrodynamic radius is in the range of 75 nm to about 200 nm, period of time is less than 130 minutes, is about 120 minutes, the first temperature is 70°C, and the second temperature at about 21°C.

Claims 1-9, and 11-14 are drawn to an aqueous dispersion of hydrogel nanoparticles comprising, interpenetrating polymer network (IPN) nanoparticles, wherein each IPN nanoparticles comprises a first polymer network interpenetrating a second polymer network, and an aqueous medium, wherein the first polymer comprises poly (-N-isopropylacrylamide), the second polymer comprises poly (acrylic acid), wherein the IPN nanoparticles are substantially free of shell and core polymer configuration, and the aqueous dispersion of hydrogel nanoparticles can undergo a reversible gelation in response to a change in stimulus applied thereon, wherein the aqueous dispersion of hydrogel nanoparticles further comprising a biologically active material, a drug, wherein the stimulus is temperature, wherein the temperature change above a gelation temperature (Tg) induces a volume phase transition of the IPN nanoparticles, resulting in an inverse thermo-thickening property of the aqueous dispersion of hydrogel nanoparticles, (and wherein above the Tg the first polymer network consists of cross-linked polymer chains inside each nanoparticle, and the second polymer network consist of a cross-linked system of the nanoparticles), wherein the inverse thermo-thickening property is a transformation from a low viscous fluid to a gel when heated above the Tg, the Tg is about 34°C, the first polymer comprises poly (-N-isopropylacrylamide), the second polymer comprises poly (acrylic acid), the IPN nanoparticles have a uniformed sized hydrodynamic radius, the average hydrodynamic radius is in the range of 75 nm to about 200 nm, wherein the weight ratio of the first polymer and the second polymer in IPN nanoparticles is about 1:1.88, and total polymer concentration from about 1.25 wt% to about 5.25 wt% in distilled water.

Jones et al. teach a method of preparing an interpenetrating polymer network of nanoparticles, comprising providing a first polymer nanoparticles prepared by mixing first monomer, a surfactant, a first cross linking agent, and first initiator at a first temperature (p.8301 2nd column 3rd and 4th paragraphs and p.8302 1st column 1st paragraph, p.8302 1st column end paragraph lines 1-3 and 16), adding to the first polymer nanoparticles a second monomer, a second cross linking agent, a second initiator and an activator, forming a nanoparticle solution wherein the nanoparticle solution is an aqueous solution, mixing the nanoparticles solution for a period of time at a second temperature to form the IPN nanoparticles, isolating the IPN nanoparticles (p.8302 1st column 1st, 2nd and 3rd paragraphs), wherein the first monomer, the first cross linking agent, the second monomer, and the second cross linking agent are substantially free from dissolved oxygen gas (degassing under vacuum and purging with nitrogen) (p.8302 1st column 1st paragraph line 7-8), wherein the first polymer has a low critical solution temperature of 38 °C (between 28°C and 45°C) (p.83 03 2nd column 2nd paragraph lines 5-6), polymerization temperature 70 °C (is above the LCST of the first polymer) (p.83 01 1st column end paragraph last line). Jones et al. further teach the first polymer comprises poly (-N-isopropylacrylamide) (Tg is about 34°C), the second polymer comprises poly (acrylic acid) or AAc (p.8302 1st column 2nd paragraph line 2), the period of time is 30 minute plus 45 minutes (less than 120 minutes) (p.8302 1st column 1st paragraph line 13-15), and the average hydrodynamic radius of the nanoparticles is in the range of 75 nm to about 200 nm (p.8302 2nd column Figure 2. radius vs. Temp graph, b. Y-axis, radius of particles 80-200 nm).

Jones et al. also teach an aqueous dispersion of hydrogel nanoparticles comprising, interpenetrating polymer network (IPN) nanoparticles, wherein each IPN nanoparticles comprises a first polymer network interpenetrating a second polymer network, and an aqueous medium, wherein the first polymer comprises poly (-N-isopropylacrylamide), the second polymer comprises poly (acrylic acid) or AAc (p.8302 1st column 2nd paragraph line 2), and the aqueous dispersion of hydrogel nanoparticles can undergo a reversible gelation in response to a change in stimulus applied thereon, wherein the stimulus is temperature, wherein the temperature change above a gelation temperature (Tg) induces a volume phase transition of the IPN nanoparticles (thermally induced volume phase transition) (Abstract), resulting in an inverse thermo-thickening property of the aqueous dispersion of hydrogel nanoparticles, wherein the inverse thermo-thickening property is a transformation from a low viscous fluid to a gel when heated above the Tg (about 34°C) (it must be noted that poly (-N-isopropylacrylamide) hydrogels undergoes a reversible volume phase transition at 32°C, see Cai et al. (p.169 1st column lines 10-14), the IPN nanoparticles have an average hydrodynamic radius is in the range of 75 nm to about 200 nm (p.8302 2nd column Figure 2. radius vs. Temp graph, b. Y-axis, radius of particles 80-200 nm), and 5% total polymer concentration (about 1.25 wt% to about 5.25 wt) (p. 8302 2nd column end paragraph lines 3), Jones et al. further teach wherein the first polymer and the second polymer in IPN nanoparticles have weight ratio of 9:1 (p.83 02 1st column 1st paragraph line 2).

Jones et al. also teach change in the particle size of the aqueous dispersion around 30 nm (at pH 6.5) when it is heated from below a volume phase transition

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temperature to above a volume transition temperature (about 34°C), the magnitude of the particle (p. 8304 Figure 5, Deswelling curves for particle at pH 6.5, the 1st curve on the top, radius change around 34°C, decrease in the magnitude of the particle size change, and the temperature on y-axis of the graph, and p. 8303 2nd column 3rd paragraph lines 13-15).

Jones et al. do not teach the second temperature is below the low critical solution temperature of the first monodispersed polymer, the second temperature at about 21°, mixing the isolated IPN nanoparticles with a biologically active material at a third temperature, third temperature is below a gelation temperature (T_g) of the IPN nanoparticles in an aqueous mixture, the biologically active material is a drug, wherein the IPN nanoparticles are substantially free of shell and core polymer configuration, wherein the first polymer and the second polymer in IPN nanoparticles have weight ratio of about 1:1.88. However, Jones et al. teach that at 70°C temperature (polymerization temperature) polymer interpenetration was low and that polymerization inside the nanoparticles can be hindered (p.8302 1st column end paragraph lines 17-19). Therefore, a person of ordinary skill in the art at the time the invention was made, would have recognized the problem with increased temperature in the Jones et al. method.

Kurisawa et al. teach using interpenetrating polymer network (IPN)-structured hydrogels as a drug microreservoir (as a model of a drug substrate), a phase morphology in the IPN-structured hydrogels was varied with the preparation temperature, i.e. above or below the sol-gel transition temperature (T_{trans}) of gelatin (Abstract, and p.194 2nd column 1st paragraph). Kurisawa et al. teach the IPN-structured

hydrogels were prepared below or above the T_{trans} of gelatin and their enzymatic degradability was examined. Dual-stimuli-responsive degradation was achieved in the IPN-structured hydrogels were prepared below T_{trans} having increased miscibility and the dual-stimuli-responsive degradation of Gtn-Dex hydrogels was closely related to the miscibility between Gtn and Dex networks (p.192, 1st column last paragraph and 2nd column 1st paragraph). Kurisawa et al. further teach regulated LM release was achieved in the IPN-structured hydrogel prepared below the T_{trans} , and although LM release from IPN-structured hydrogel prepared above the T_{trans} was observed, the difference in the LM release behavior is though to be have been caused by enzymatic degradability of the hydrogels, being closely related to physical chain entanglements between chemically different polymer networks (p.199 2nd column last paragraph, Conclusion).

Jones et al. further teach in core-shell systems one polymer has a chemical or mechanical influence over the swelling of the other polymeric component and display complex phase transition (p.8301 Introduction 1st column 2nd paragraph lines 9-11 and 2nd column lines 1-4).

Cai et al. teach inside IPN hydrogels, each network may retain its own properties, whereas the proportions of the networks are varied independently. The combined properties of the IPNs can be controlled by the ratios of their component monomers (p.170, 2nd column 2nd paragraph).

Therefore, a person of ordinary skill in the art at the time the invention was made, recognizing that high polymerization temperatures can hinder the polymer interpenetration and that phase morphology in the IPN-structured hydrogels was varied

with the preparation temperature, would have been motivated to modify the method and the composition (dispersion of hydrogel nanoparticles) as taught by Jones et al. by optimizing and lowering the temperature according to teach teachings of Jones et al. in order to provide a method of preparing a dispersion of hydrogel nanoparticles and an dispersion of hydrogel nanoparticles with a reasonable expectation of success in forming a higher polymer interpenetration . Moreover, a person of ordinary skill in the art at the time the invention was made would have been motivated to modify the method and the dispersion of hydrogel nanoparticles as taught by Jones et al. by adding a drug at a third temperature below a gelation temperature of the IPN nanoparticles in an aqueous mixture, according to the teachings of Kurisawa et al. with a reasonable expectation of success, because Kurisawa et al. teach IPN-structured hydrogels can be prepared below the T_{trans} , and drug release using IPN-structured hydrogel prepared below gel transition temperature.

Accordingly, since the ratio of the first polymer to the second polymer in the IPN nanoparticles is a variable that depends on the amounts (or ratio) of the monomers being mixed (a result-effective variable), therefore this ratio in the method as taught by Jones et al. could have been optimized by routine experimentation at the time of the invention by a person of ordinary skill in the art, said person recognizing that the phase transition properties of the IPNs can be controlled by the ratios of their component monomers. The motivation as taught by Jones would be to provide a dispersion of IPN nanoparticles with less complex phase transition behavior.

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Claims 29-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cai et al. (Journal of Applied Polymer Science, 2002, Vol. 83, p.169-178) and Jones et al. (Macromolecules, 2000, Vol. 33, p.8301-8306) in view of in view of Hennink & Nostrum (Advanced Drug Delivery Reviews, 2002, Vol. 54, p.13-36).

Claims 29-47 are drawn to a method of preparing a nanocluster of cross-linked IPN nanoparticles comprising, providing a dispersion of IPN nanoparticles, adding a first cross linking agent and a second cross linking agent to the dispersion of the IPN nanoparticles, heating the IPN cross linking solution to a first temperature for a period of time, wherein the IPN nanoparticles have uniformed size and comprise a first polymer network interpenetrating a second polymer network, mixing the nanocluster of cross-linked IPNs with a biologically active material at a second temperature, the first polymer comprises of poly(-N-isopropylacrylamide) and the second polymer comprises poly(acrylic acid), first cross-linking agent comprises EDAC and second cross linking agent comprises adipic acid dihydrazide, heating at a first temperature, about 44°C, for about 25-45 min (33-37 min), mixing cross-linked IPNs with a biologically active material at about 33°C, and hydrodynamic radius in the range from 225 nm to about 240 nm, a nanocluster of cross-linked IPN nanoparticles comprising: at least two IPN nanoparticles linked by a cross-linking group, a first polymer network interpenetrating a second polymer network, the cross linking group is adipic acid dihydrazide, wherein each IPN nanoparticles have a uniformed sized and an have an average hydrodynamic radius of nanoparticles is in the range of 155 nm to about 1000 nm.

Cai et al. teach a method of preparing a nanocluster of cross-linked nanoparticles and a nanocluster cross-linked nanoparticles (particle size 500 to 700 nm) (Abstract, and p. 172 2nd column end paragraph line 2). Cai et al. teach the microgel nanoparticles are ionic particles because of the carboxylic charge on acrylic acid (AA), in these microgel particles the AA groups tend to lie on the surface of the particles, and NIPAAm groups lie toward the inside, this prevents aggregation between microgel particles and makes the microgel particles stable in the aqueous solutions. In this conformation, the carboxyl groups of on the microgel particle surface can also be further cross-linked under suitable conditions, forming interpenetrating network structure (p.172 2nd column last paragraph and p.173 1st column). Cai et al. further teach mixing the particles with a biologically active material (bovine serum albumin, a protein) at different temperatures (p.172, 2nd column 1st paragraph). Cai et al. teach to increase the volume and surface area of the bulk hydrogels, hydrogels can be synthesized at temperatures above the LCST of the polymer by heating the reaction near the end of the polymerization (p.169 2nd column last paragraph).

Cai et al. do not teach a dispersion of IPN nanoparticles, the first cross-linking agent comprises EDAC and second cross linking agent comprises adipic acid dihydrazide, heating at a first temperature about 44°C, for about 25-45 min (33-37 min). However, as mentioned immediately above, Jones et al. teach preparing an aqueous dispersion of IPN nanoparticles, the first polymer comprises of poly(-N-isopropylacrylamide) and the second polymer comprises poly(acrylic acid), and heating at a first temperature about 44°C, for about 25-45 min (30 minutes). Jones et al. also

teach change in the particle size of the aqueous dispersion around 30 nm (at pH 6.5) when it is heated from below a volume phase transition temperature to above a volume transition temperature (about 34°C), the magnitude of the particle (p. 8304 Figure 5, Deswelling curves for particle at pH 6.5, the 1st curve on the top, radius change around 34°C, decrease in the magnitude of the particle size change, and the temperature on y-axis of the graph, and p. 8303 2nd column 3rd paragraph lines 13-15).

Hennink & Nostrum teach cross-linking agents EDC (or EDAC) is a highly efficient reagent to crosslink water-soluble polymers with amide bonds, and hydrogel formation by using a less toxic cross linking agent adipic acid dihydrazide in the presence of a drug, for aldehyde-mediated crosslinking (p.20 1st column 2nd paragraph) (p.19, 1st column lines 20-23).

Therefore, a person of ordinary skill in the art at the time the invention was made would have been motivated to apply the prior art teachings and to use the method of Cai et al. to cross-link the dispersion of IPN nanoparticles of Jones et al. in order to provide a method of preparing a nanocluster of cross-linked IPN nanoparticles and a nanocluster of cross-linked IPN nanoparticles with a reasonable expectation of success, because Cai et al. teach cross-linking nanoparticles to form a larger hydrogel/nanocluster. The motivation would be to create a larger network structure.

Moreover, a person of ordinary skill in the art at the time the invention was made, would have been motivated to try and use the cross-linking agents EDC and adipic acid dihydrazide as taught by Hennink & Nostrum to cross-link the dispersion of IPN nanoparticles according to the teachings of Cai et al. in order to provide a method of

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preparing a nanocluster of cross-linked IPN nanoparticles and a nanocluster of cross-linked IPN nanoparticles, because Hennink & Nostrum teach EDC and adipic acid dihydrazide can be used to form hydrogels. The motivation as taught by Hennink & Nostrum would be to cross-link different functional groups, and low toxicity of adipic acid dihydrazide.

Answer to Arguments

Applicant's arguments filed on 09/22/2009 have been fully considered but they are not persuasive.

With respect to the rejection of claims 1-9, and 11-47 under 35 U.S.C. 103(a), Applicant arguments that claim 1 has been amended and Jones et al. does not suggest the current method or aqueous dispersion, and that none of the references suggest that the current method and aqueous dispersion could have been achieved through temperature manipulation. These arguments have been fully considered but are not found persuasive.

Because, as mentioned immediately above, Jones et al. teach change in the particle size of the aqueous dispersion around 30 nm (at pH 6.5) when it is heated from below a volume phase transition temperature to above a volume transition temperature (about 34°C), the magnitude of the particle (p. 8304 Figure 5, Deswelling curves for particle at pH 6.5, the 1st curve on the top, radius change around 34°C, decrease in the magnitude of the particle size change, and the temperature on y-axis of the graph, and p. 8303 2nd column 3rd paragraph lines 13-15), and because a person of ordinary skill in the art at the time the invention was made would have recognized that the temperature

of the polymerization in the Jones's method is a result-effective-variable and could have been optimized.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kade Ariani whose telephone number is (571) 272-6083. The examiner can normally be reached on IFP.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kade Ariani
Examiner
Art Unit 1651

/Leon B Lankford/
Primary Examiner, Art Unit 1651